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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/728,547

12/05/2003

Ronald W. Marsh

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08/04/2009

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EXAMINER

GRAY, PHILLIP A

ART UNIT

PAPER NUMBER

3767

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/728,547	<b>Applicant(s)</b> MARSH ET AL.	
	<b>Examiner</b> Phillip Gray	<b>Art Unit</b> 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4/1/09.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This office action is in response to applicant's communication of 4/1/2009. This action is non-final.

#### *Response to Arguments*

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, and 19 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chu et al. (U.S. 5,397,310). Chu discloses a catheter introducer sheath assembly and discloses a needle (as shown in figures 11-15) comprising an elongate tube (120) with sharpened tip, a hub (near 2a or 4 as in figure 3) and a resilient member (22 shown in figure 3) and a clamp (12/24 as in figure 3), and where the clamp is in an open position (4 or 4b) and a clamp position (shown in figure 4a wherein "the clamp causes a strain to at least a portion of the resilient member thereby **reducing but not occluding**, the inner diameter of the

opening through at least a portion of the resilient member", further a spinal needle (124) is shown whereby the spinal needle may become fixed but not occluded (see figure 11a).

Concerning the claim language, it is examiners position that the elongate tube is "stiff" and the tube "has a sufficient stiffness to penetrate a patients tissue and be placed in a patient's epidural space". The term "stiff" is a term of degree and the prior art Chu stiff tube (120) appears to hold its shape and is not flexible (see figure 11) and would be fully capable of piercing tissue (see figure 6-6e) and be placed in a epidural or permitting deliver to a patient's subarachnoid space (column 1 lines 60-67 disclose positioning in bodily through-passage or channels. It is examiners position that these through-passages or channels would be epidural or subarachnoind space.

Examiner is reading this to be a functional limitation. It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In addition, where their is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, applicant is required to believe that the

subject matter shown in the prior art reference does not possess the characteristic relied upon.

But in the alternative if not inherent that Chu tube is stiff and capable of penetrating tissue, then it would have been an obvious modification of Chu. Chu discloses the claimed invention except for the stiff tube capable of penetration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to the tube stiff for penetrating tissue, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). *In the instant case it would be used to penetrate tissue directly with the device rather than using a guidewire.*

The elements disclosed in Chu and the prior art of record are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made. See rejection discussion below.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu (U.S. 5,397,310) in view of Mc Wha et al. (U.S. Patent Number 5,480,389). **In the alternative** if not anticipated by Chu or obvious over Chu, Chu in view of McWha teaches the use of an epidermal set and clamping device with a stiff needle for penetrating tissue. Chu discloses the device see above, but McWha discloses a stiff needle for penetrating tissue.

Chu discloses the claimed invention except for the stiff needle for penetrating tissue. McWha teaches that it is known to use a stiff needle for penetrating tissue as set forth in paragraphs at column 6 lines 15-65 to provide a means to penetrate tissue or a "particular anesthetic application". It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Chu with a stiff needle as taught by McWha, since such a modification would provide the system with a stiff needle for providing a means to penetrate tissue or a "particular anesthetic application" as in the McWha device.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mc Wha et al. (U.S. Patent Number 5,480,389) in view of Schaffer (U.S. Patent Number

Art Unit: 3767

5,429,616). McWha discloses a spinal epidural needle set (figure 3) comprising an elongate tube (14) with a sharpened distal end (15), an attached hub (22,26,34,51,40) and a spinal needle (12) and indicia for location (34). The epidermal and spinal needle system is fully capable of performing all the associated functional language and claim limitations. Schaffer discloses a hub/needle/catheter (see figures 2 and 5) with a resilient member (50) permanently mounted within a hub (26), and a deformable U-shaped clamp with living hinge (24) with a releasable latch push tab (60) and support arms, that is oriented for perpendicular movement to the elongate tube. Further the resilient member defines a radiused portion and the readiused portion of the pair of legs (48) has a radius substantially the same as the radiused portion of the resilient member, and a second radiused portion (figures 3-6). The resilient member and clamp of Schaffer are fully capable of performing all the associated functional language and claim limitations.

Mc Wha discloses the claimed invention except for the resilient member and clamp. Schaffer teaches that it is known to use a resilient member and clamp as set forth in paragraphs beginning at columns 1-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the epidermal needle system as taught by Mc Wha with the resilient member and clamp as taught by Schaffer, since such a modification would provide the epidermal needle system with the resilient member and clamp for providing inward collapsing of the side wall portion and to **reduce but not occlude** the apparatus.

Concerning the claim language that the clamp causes a “strain to at least a portion of the resilient member thereby **reducing but not occluding...**”, It is examiners position that the resilient member and clamp of Schaffer would be fully capable and known (to a PHOSITA) that the clamp would **reduce but not occlude** the inner diameter of the opening. As evidenced in figures 3 through 6 of Schaffer, the clamp has a range of operation that causes the inner diameter to be from fully open to occluded, but also has an intermediary position of a “reduced” in diameter state (when not fully open or fully closed). Therefore it is examiners position that the clamp would be fully **capable of reducing but not occluding**.

In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the clamp reduce the inner diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955). In this case it would be obvious for a person having ordinary skill in the art at the time of the invention, to modify the range of the clamp (how closed it becomes or how much it reduces the inner diameter) in order to limit the amount of fluid flow through an inner diameter or reduce the space to secure the clamp to another body.

### ***Conclusion***



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767